

**UNITED STATES DEPARTMENT OF COMMERCE****U.S. Patent and Trademark Office**

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
---------------------------------	-------------	---	---------------------

EXAMINER

ART UNIT	PAPER
----------	-------

54510101

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Examiner hereby confirms that this application is not abandoned since the response to the final action was filed on 11/17/05. Following a telephonic interview with the attorney and required amendments this application was allowed.

Notice of Allowability

Application No.

10/622,283

Examiner

Kagnew H. Gebreyesus

Applicant(s)

STERN ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/17/05.
2. ☒ The allowed claim(s) is/are 34-42, 44-54, 56-68, 70-82, 84-96, 98-110, 112-114 with amendments.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>12/08/2005</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Paula Borden on December 8, 2005.

1. The following is an examiner's statement of reasons for allowance:

In claim 34, 47, 59, 73, 87, 101:

Replace: "...human plasma hyaluronidase..." with "*...naturally occurring human plasma hyaluronidase...*"

Replace: "...wherein said polypeptide is glycosylated,..." with

"...wherein said polypeptide is at least 60%, by weight, free from the proteins and naturally-occurring organic molecules with which it is naturally associated and wherein said polypeptide is glycosylated,..."

In claims 40, 42, 52, 53, 61, 67, 75, 81, 94, 96, 108 and 109 replace:

■ at least about -- with -- *at least*--.

In claim 47 replace:

- above about -- with -- *above* --

In claim 87, 101 replace:

- "... below about..." with "... below..."

Canceled claims:

43, 55, 69, 83, 97 and 111 are cancelled given that these claims are encompassed in the limitation of the independent claims.

Reason for allowance:

The claims directed to a substantially purified preparation of naturally occurring biologically active human plasma hyaluronidase enzymes as disclosed on page 13 line 2-24. Applicant's submission of a declaration under 1.132 and the clarification provided contrasting their plasma hyaluronidase preparation and Affify's plasma hyaluronidase purification in terms of the steps, starting material and most importantly the activity/unit enzyme is persuasive. In addition although the prior art (Bader et al.) teaches a Human tumor suppressor (LUCA-1) mRNA and deduced amino acid sequence identical to the human plasma hyaluronidase identified by applicants, the disclosure does not teach a human plasma hyaluronidase enzyme or a recombinant human plasma hyaluronidase enzyme substantially purified 6×10^5 rTRU as shown by the applicants. Therefore the claims drawn to a substantially pure naturally occurring human plasma hyaluronidase enzyme is allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

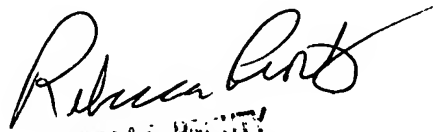
fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagne H. Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy Ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kagne H. Gebreyesus PhD.


REBECCA E. PROST
PRIMARY EXAMINER
GROUP 1800
1620